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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,057	06/26/2007	Michelle Alfa	81190-3002	5997

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Ade & Company  
1795 Henderson Highway  
P.O.Box 28006  
Winnipeg Menitoba, R2G OP1  
CANADA

EXAMINER

ARCHIE, NINA

ART UNIT PAPER NUMBER

1645

MAIL DATE DELIVERY MODE

11/16/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

### Application No.

10/564,057

### Applicant(s)

ALFA, MICHELLE

### Examiner

Nina A. Archie

### Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**  
***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

1. Group I: claims 1-7 drawn to a pharmaceutical composition.
2. Group II: claims 8-14 drawn to a method of preparing a pharmaceutical composition.
3. Group III: claims 15-21 drawn to a method of treating or preventing a gastrointestinal illness.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of Group I is a pharmaceutical composition comprising: polyclonal antibodies directed against at least one enteric pathogen; and a probiotic. The technical feature of Group 1 is anticipated by Chandler et al. WO 97/20577. Chandler et al. teach a pharmaceutical composition comprising: polyclonal antibodies (i.e. colostrum or egg yolk) directed against at least one enteric pathogen; and a probiotic (see pgs. 5-8).

4. Group II is a method of use of the technical feature in Group I, a pharmaceutical composition.

5. Group III is a method of use of the technical feature in Group I, a pharmaceutical composition.

The technical feature of Group I, a pharmaceutical composition is known in the art. Group I lacks unity with Groups II-III, because the technical feature of Group I is anticipated by the art and therefore not "special" within the meaning of PCT Rule 13.2

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because it does not provide for a contribution that the claimed invention makes over the art.

### **Election of Species**

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. If the Applicant elects Group I, Group II, or Group III, the Applicant is required to elect a single individual species from Group I listed below.

Species-Enteric Pathogen;

- 1) *Aeromonas hydrophilla*
- 2) *Bacillus cereus*,
- 3) *Vibrio parahaemolyticus*
- 4) *Vibrio cholerae* O1
- 5) *Vibrio cholerae* non-O1
- 6) *Vibrio vulnificus*
- 7) *Salmonella enterica*
- 8) *Salmonella typhi*
- 9) *Salmonella paratyphi*
- 10) *Salmonella enteritidis*
- 11) *Salmonella choleraesuis*
- 13) *Salmonella typhimurium*
- 14) *Clostridium difficile*
- 15) *Clostridium botulinum*
- 16) *Clostridium perfringens*
- 17) *Staphylococcus aureus*
- 18) *Escherichia coli* ETEC
- 19) *Escherichia coli* EPEC
- 20) *Escherichia coli* EHEC
- 21) *Escherichia coli* EaggEC
- 22) *Escherichia coli* UPEC

- 23) Escherichia coli EIEC
- 24) Campylobacter jejuni
- 25) Campylobacter coli
- 26) Campylobacter lari
- 27) Campylobacter fetus,
- 28) Yersinia enterocolitica
- 29) Yersinia pestis
- 30) Yersinia pseudotuberculosis
- 31) Plesiomonas shigelloides
- 32) Listeria monocytogenes
- 33) Enteric viruses
- 34) Rotavirus
- 35) Norwalk-like viruses
- 36) Enteric adenoviruses
- 37) Coronavirus
- 38) Non-enveloped enteroviruses
- 39) Enteric parasites
- 40) Enteric fungi
- 41) Cryptosporidium
- 42) Cyclospora.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

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Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina Archie whose telephone number is 571-272-9938. The examiner can normally be reached on M-F 8:30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Bruce Campell can be reached on 571-272-0794. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Nina Archie

Patent Examiner

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Remsen 3B31



MARK NAVARRO  
PRIMARY EXAMINER